UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,429	11/29/2002	Jane E Aubin	3477.95	6914

20792 7590 12/22/2005

MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 12/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,429	AUBIN ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2 and 16-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2 and 16-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Status of Application, Amendments and/or Claims

The amendment filed 13 October 2005 has been entered in full. Claims 1 and 3-15 and are cancelled. New claims 16-18 are added. Claims 2 and 16-18 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The objection to claim 2 as set forth at page 7 of the previous Office Action (13 April 2005) is *withdrawn* in view of the amendment (13 October 2005).

Claim Rejections - 35 USC § 112, First Paragraph, Enablement

Claims 2 and new claims 16-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The basis for this rejection (for claim 2) is set forth at pages 3-5 of the previous Office Action (13 April 2005).

Applicant argues that the specification shows a positive relationship between ERRα expression and osteoblast differentiation. Applicant argues that it is irrelevant

whether Applicants have also demonstrated a correlation between estrogen, vitamin D3 or TGFβ-induced ERRα expression and osteoblast differentiation.

Applicant's arguments have been fully considered but are not deemed persuasive. Claim 2 is directed to a method of increasing osteoblast differentiation by *administration of an ERRα agonist*. Contrary to Applicant's assertion, the instant specification fails to teach increased osteoblast differentiation upon administering an ERRα agonist. The instant specification demonstrates a positive relationship between ERRα expression and osteoblast differentiation. This, however, is not tantamount to the instant method claim. Suetsugi *et al.,* Mol. Cancer Res. 1:981-991 (2003) (references submitted by Applicant) teach agonistic ligands of ERRα by showing *activation* of the ERRα receptor via a luciferase reporter gene (For example, see Suetsugi *et al.* Figure 5). Not only does the instant specification fail to demonstrate ERRα activity upon agonist binding, it also fails to demonstrate increased osteoblast differentiation upon agonist binding.

In response to the Examiner's argument that the term ERRα agonist can encompass a large genus of molecules and the specification does not indicate a representative number of agonists, Applicant argues that the instant specification does teach methods for identifying an ERRα agonist. Applicant cites pages in the specification. Applicant maintains that the application teaches that agonists or antagonists of ERRα may be identified by screening for their effects in an assay for ERRα activity. Applicant argues that ERRα activity may be measured by examining osteoblast differentiation in the cell systems described in the examples of the

application. Applicant contends that other methods of identifying ERRα agonists are known to those of skill in the art. Applicant cites Suetsugi *et al.* (reference discussed above) and Zuercher *et al.,* J. Med. Chem. 48:3107-3109 (2005). Applicant maintains one of skill in the art using known methods could identify ERRα agonists without undue experimentation and that claim 2 is enabled by the specification as filed.

Applicant's arguments have been fully considered but are not deemed persuasive. The instant method *is not* directed to a method of identifying agonists (i.e. screen). The instant method is directed to increasing osteoblast differentiation in a mammal comprising administering an ERRα agonist. The instant method *requires the use* of undisclosed agonists. Furthermore, an assay for finding a product is not equivalent to a positive recitation of how to make them. The specification fails to indicate that a representative number of structurally related compounds are disclosed and therefore, the artisan would not know the identity of a reasonable number of representative compounds falling within the scope of the instant claim and would not know how to make them. As was stated in the last Office Action, the term ERRα encompasses a large genus of molecules. The specification does not address how to make and use chemicals, compounds, nucleic acid, lipids, macromolecules, etc that would bind the ERRα receptor in a subject to cause osteoblast differentiation. One skilled in the art would not have been able to have practiced the process steps recited in the claim without undue experimentation. The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description

Claims 2 and new claims 16-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis for this rejection (for claim 2) is set forth at pages 5-7 of the previous Office Action (13 April 2005).

Applicant argues that one skilled in the art would find that the Applicants were in fact in possession of the claimed invention at the time of filing. Applicant maintains that the instant specification teaches methods for screening and identifying candidate compounds for their activity as ERRα agonists. Applicant argues that it was well understood by those of skill in the art at the priority date that one could screen for agonists using a combination of methods, firstly a biological assay and then a molecular-biochemical study to determine if an observed biological effect was due to agonism of ERRα. Applicant argues that all of the assays are routine, well within the purview of the skilled worker and not involving undue experimentation, giving Applicants' possession of the claimed invention.

Applicant's arguments have been fully considered but are not deemed persuasive. In order to evidence possession of the claimed method, one would need to demonstrate possession of its process steps which require the use of undisclosed compounds. There is no structural element correlative with the function. No structural or

functional characteristics of such an agonist are provided, nor is there any indication that Applicant had possession of any ERRα agonists. There is insufficient descriptive support for the genus ERRα agonists. The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

New Claim Rejections - 35 USC § 112, First Paragraph, Written Description, New Matter

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The specification as originally filed does not provide support for the invention as now claimed: "wherein the agonist is administered **systemically**". Applicant's amendment, filed 13 October 2005, asserts that no new matter has been added and directs support to page 16, lines 14-17 and page 19, lines 15-18, for the written description for the above-mentioned "limitations". The wording of the instant claim is not readily apparent from said sections.

The specification does not provide direction for the instant methods encompassing the above-mentioned "limitations" as they are currently recited. The instant claim now recites limitations which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as-filed.

Applicant is required to cancel the new matter in the response to this Office action. Alternatively, Applicant is invited to provide specific written support for the "limitations" indicated above or rely upon the limitations set forth in the specification as filed.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RMD
12/14/05

Marianne P. Allen

MARIANNE P. ALLEN
PRIMARY EXAMINER

12/15/05

AU1647